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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/820,553 | 04/08/2004 | Wilfried Fischer | 29473/11372A | 8366 |
| 4743 7590 11/28/2007 MARSHALL, GERSTEIN & BORUN LLP 233 S. WACKER DRIVE, SUITE 6300 SEARS TOWER CHICAGO, IL 60606 | | | EXAMINER GILBERT, ANDREW M | |
| | | | ART UNIT 3767 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,553

Applicant(s)

FISCHER ET AL.

Examiner

Andrew M. Gilbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 6, 7, 11-14 and 16-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 12, 13, 16-18, 21, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 2, 6, 7, 11, 14, 19, 20, 22-24 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgements

1. This office action is in response to the reply filed on 8/31/2007.
2. In the reply, the Applicant filed a Terminal Disclaimer to U.S. Patent No. 6757560 that has been APPROVED on 11/19/2007. Thus, the rejection is obviated.
3. The Applicant filed arguments discussing the claim objection of claims 1 and 16. The arguments are persuasive and the objection has hereby been withdrawn.
4. Additionally, the Applicant filed arguments showing that Avarhami (6148232) is improperly considered a prior art reference under MPEP 2136.05, 715.02, 706.02(b). The arguments are persuasive and the rejection is hereby withdrawn.
5. Thus, claims 1, 2, 4, 6, 7, 11-14, 16-27 are pending for examination.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4, 12-13, 16-18, 21, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corish et al (5533995) in view of Hofmann et al (6192270).
8. In reference to independent claim 1, Corish et al discloses a transdermal delivery system comprising: a carrier layer (23) impermeable to a substance to be delivered and comprising one or more electrodes (14); a reservoir (12) containing said substance to be delivered, the reservoir being formed by a contact adhesive (col 3, lns 52-col 4, lns

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35; and discussion below in Response to Arguments) and provided stacked between the carrier layer and one or more counter electrodes (23, 12, 12, 13; Fig 1); a battery (17; col 5, lns 57-62); an integrated controller microchip (18; col 6, lns 9-13, 54-64; col 8, lns 66-67) that is fixed to the carrier layer and programmable to a prescription; a reading and writing device (18; col 6, lns 9-13, 54-64; col 8, lns 66-67).

9. In reference to independent claim 16, Corish et al discloses a transdermal delivery system comprising: a carrier layer (23) impermeable to a substance to be delivered; a membrane (13) permeable to said substance to be delivered; a reservoir (12) containing said substance to be delivered, the reservoir being provided stacked between the carrier layer and the membrane (Fig 1); a layer (15, col 3, lns 52-col 4, lns 35, col 7, lns 3-6; and discussion below in Response to Arguments) consisting of a pressure-sensitive contact adhesive applied to the side of the membrane remote from the reservoir; a battery (17); an integrated controller microchip (18; col 6, lns 9-13, 54-64; col 8, lns 66-67) fixed to the carrier layer; and a reading and writing device (18; col 6, lns 9-13, 54-64; col 8, lns 66-67), wherein the carrier layer and the membrane comprise one or more electrodes such that the one or more electrodes of the membrane serve(s) as counterelectrode(s) to the one or more electrodes of the carrier layer (col 8, lns 29-39).

10. In reference to claim 4, 17 (see (col 3, lns 22-29)); claim 12, 25 (see (18; col 6, lns 9-13, 54-64; col 8, lns 66-67)); claim 13, 26 (see (col 5, lns 58-62)); claim 18 (see (col 3, lns 52-col 4, lns 35)); claim 21 (see (col 8, lns 12-18)).

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11. However, Corish et al does not expressly disclosing a removable film. Hoffman et al teaches that it is known to have a removable film (col 3, lns 51-54) for the purpose of providing a protective cover that can be peeled off before use (col 3, lns 51-54). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Corish et al with the removable film as taught by Hofmann et al for the purpose of providing a protective cover that can be peeled off before use (col 3, lns 51-54).

Allowable Subject Matter

12. Claims 2, 6, 7, 11, 14, 19, 20, 22-24 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments filed 8/31/2007 have been fully considered but they are not persuasive.

14. The applicant argues that:

- i. The Examiner did not discuss Corish et al disclosing a contact adhesive meeting the requirements of MPEP 2143.03 and assumes that the Examiner is disclosing the contact adhesive as being inherent in Corish et al (Remarks, pg 8). Further, Corish et al teaches away from a contact adhesive (Remarks, pg 9, paragraph 3).

ii. Corish et al does not disclose a pressure-sensitive contact adhesive applied to the side of the membrane remote from the reservoir (Remarks, pg 9).

iii. The Examiner has not shown that the prior art would provide a reasonable expectation of success in modifying Corish et al with an adhesive applied to a membrane. Rather Corish teaches away from such use (Remarks, pg 10, paragraph 4).

15. In response to the applicant's argument (i), the Examiner notes that the Examiner explicitly disclosed the Examiner's interpretation of a contact adhesives meeting the requirements of MPEP 2143.03. In the discussion of Avarhami (see paragraph 9) the Examiner disclosed:

"wherein the Examiner notes that the Examiner has considered a contact adhesive to be any substance that adheres on contact and the disclosed reservoir of Avarhami is fully capable of being a contact adhesive as the reservoir (74) adheres to both sides of the electrode patch (70) in Fig 1b)"

Thus, a reservoir (12, col 3, lns 52-col 4, lns 35) of Corish et al consisting of a reservoir formed by a contact adhesive is explicitly disclosed with the Examiner's interpretation. The layer is composed of a gel and is adhered to the sides of the electrodes (13, 14, Fig 1). The point is moot that Corish et al uses other methods of adhering the device to the patient's skin and thus, evidently, teaches away from use of a contact adhesive. The reservoir being comprised by a contact adhesive reads on the applicant's claim limitations. The fact that additional means are used to secure to the skin is moot.

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16. In response to the applicant's argument (ii), the Examiner notes that the reservoir (12) has a membrane (13) and a layer (15) that is disclosed as a gel that meets the Examiner's interpretation of contact adhesive discussed above (i), including being pressure sensitive because the gel is fully capable of adhering to the membrane (13) and the skin under pressure.

17. In response to the applicant's argument (iii), the Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the pressure sensitive adhesive is not an additional intervening layer added to the device of Corish et al. Rather, Corish et al explicitly discloses using the transit chamber in the embodiment. It is a moot that the transit chamber retards transport because the expectation of success is still prevalent and valid in Corish et al. Corish et al still function as a controlled drug delivery device with the transit chamber. Corish et al additionally meets the Applicant's claim limitations. The rejection is maintained.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

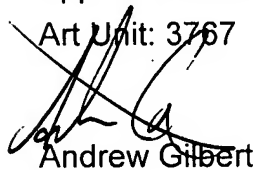
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

